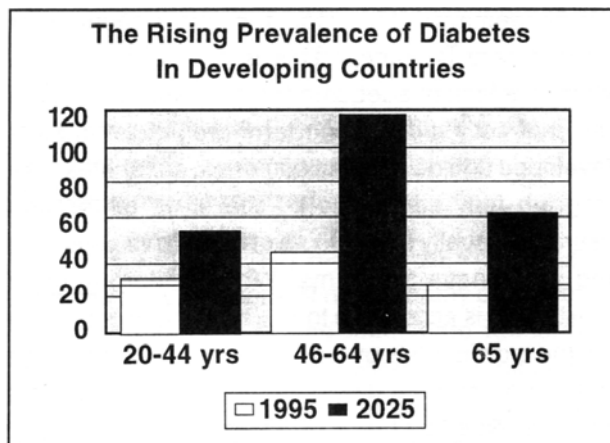


# CONSENSUS GUIDELINES – MINIMUM BASIC CARE FOR PERSONS WITH DIABETES MELLITUS \*

## BACKGROUND DATA

### The rising burden of diabetes

The prevalence of diabetes is steadily increasing world wide particularly in the developing countries. There were an estimated 84 million person with diabetes in the developing world in 1995. The Indian sub continent accounted for a quarter of them. This number is likely to increase three folds to 226 million. Type 2 diabetes is the commonest form of diabetes seen worldwide.



**Figure 1 : The rising burden of diabetes**

This form of diabetes is considered a life style disease. The underlying genetic predisposition gets unmasked in the presence of the right (wrong) environmental factors such as sedentary lifestyle, change in traditional food habits from coarse simple meals to highly refined calorie dense food, and stress of urban living.

The prevalence of type 2 diabetes in India has been steadily increasing in urban areas from a low 2.1% reported in early 1970 [1] to a whopping 11.6% [2] in 1996 in the adult population. Moreover, there is an equally large pool of persons with IGT, many of whom will go on develop type 2 diabetes in the future [2]. There is evidence to suggest that prevalence of type 2 diabetes is increasing even in rural areas [3]. The rapid increase in population, increased longevity and high ethnic susceptibility to diabetes, coupled with rapid urbanization and changes from traditional lifestyles will most likely

trigger a diabetes epidemic [4]. The WHO estimates that there were 19.4 million persons with diabetes in India in 1995 and that this number is likely to be 57.2 million in 2025. [5] These figures are based on lower estimated prevalence rates than currently seen. Based on current estimates there are about 25 million persons with diabetes of which only 3.6 million receive pharmacological treatment [6]. Moreover, type 2 diabetes amongst Indians is being increasingly seen in younger, less obese persons than reported in the West. The earlier occurrence, coupled with delayed diagnosis and improper care may lead to high complication rates, greater productivity loss and consequently higher costs.

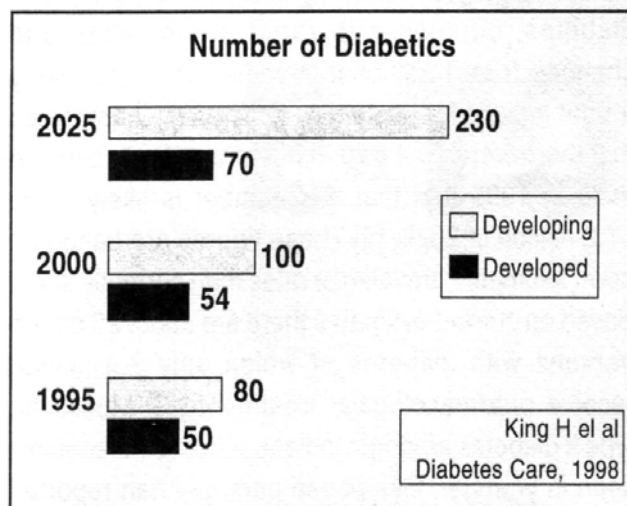
**Table 1 : Countries with highest number of adults with diabetes (millions)**

Country	1995	Country	2025
India	19.4	India	57.2
China	16.0	China	37.6
USA	13.9	USA	21.9
Russia	8.9	Pakistan	14.5
Japan	6.3	Indonesia	12.4
Brazil	4.9	Russia	12.2
Indonesia	4.5	Mexico	11.7
Pakistan	4.3	Brazil	11.6
Mexico	3.8	Egypt	8.8
Ukraine	3.6	Japan	8.5
World Wide	135.3	World Wide	300.0

*King H et al, Diabetes Care 1998*

Type 2 diabetes mellitus is associated with substantial morbidity and mortality from microvascular and macrovascular complications. The risk of developing diabetic micro-vascular complications is related to the degree of hyperglycemia, with the risk increasing at values only slightly above the normal range for haemoglobin A1c (HbA1c) and progressively increasing as hyperglycaemia worsens [7]. There does not appear to be a threshold glucose level for micro-vascular complications that is significantly above the accepted upper limits of normal for fasting and post-prandial glucose concentrations. [8-9].

\* Developed by Novo Nordisk Education foundation, in consultation with a nationwide faculty of diabetologists from India.



**Figure 2 : Distribution of persons with diabetes in developed and developing world (Figures in millions)**

Based on the results of the Diabetes Control and Complications Trial (DCCT) [9] in patients with type 1 diabetes, as well as the Kumamoto Study [10] and the United Kingdom Prospective Diabetes Study (UKPDS) [11] in patients with type 2 diabetes, it is generally accepted that intensive treatment that achieves normal blood glucose levels minimizes the risk of developing long-term complications of diabetes. Improving glycemic control can prevent micro-vascular complications in both type 1[9] and type 2 diabetes.[10,13] Although the relationship between macrovascular disease and glycemic control is less clear than it is for micro-vascular disease, hyperglycaemia is a macrovascular disease in type 2 diabetes. [8,13,14] In the UKPDS, there was a non significant 16% reduction in risk of myocardial infarction in the intensively treated group compared with those treated by conventional modalities. [11]

### **DIABETES HEALTH CARE DELIVERY IN INDIA**

Health care delivery in India is provided either by doctors in the health centers, clinics, district, municipal and tertiary teaching hospitals run by the central and state governments; or through private practising general practitioners, specialists in their clinics, nursing homes or large corporate hospitals. The quality and cost of care varies considerably from place to place, depending on the available resources, training and interest in diabetes of the treating doctor and the patient's ability to pay for it. Generally, care provided in government institutions is free or at low subsidized cost. These institutions

are crowded, ill equipped, and have scant resources. Due to the scant and limited resources the system is geared towards care of acute pressing illnesses. While most of them strive to do their best, given the limited resources and infrastructure for chronic diseases like diabetes, the quality of care may suffer. Those seeking medical care in the private sector pay for everything on their own as there is limited or no reimbursements. Here too the infrastructure for chronic care is limited. This is a unique situation where the lack of adequate facilities and capacity to pay, indirectly affects long term prognosis. In most developed and developing countries, a diabetes care program fully supported by the state or through insurance usually exists. Some of them have education and awareness programs. When uniformly good quality care is accessible to all, (as in many countries) it is the individual's own decision to take advantage of it or not; and the disease outcome is at least not pre determined by his/her socio-economic standing.

The prevailing poverty, ignorance, illiteracy and poor health consciousness further adds to the problem. Patients can access any level of care (primary, secondary or tertiary) based on close location, knowledge of its existence and resources. Thus many sociological factors determine long-term outcome of illness. A study of these factors and their influence on the prognosis and outcome are necessary to tackle diabetes in the community. They have also looked at perceptions and attitudes of persons with diabetes and of the diabetes care providers and their significance to proper diabetes care delivery. [6,15,16,17] Diabetes education and awareness programmes are an integral and essential part of diabetes care. There is emerging evidence that diabetes education, awareness and improving motivation for self care improves care, reduces complications and may thus reduce overall economic costs of diabetes. Assal JP [18] showed that simple measures like patient education and awareness about foot problems can bring about a remarkable reduction in amputation rates. They calculated that the cost of nine below knee amputations can pay the annual salary of 13 hospital staff responsible for the care of 400 patients; giving 820 hours of group lectures and 1100 hours of one to one teaching; 1500 foot consultations; answering 1300 telephone calls and training 75 nurses and dieticians for one week.

Using computer modeled incorporated data, from population based epidemiological studies and multi-centric clinical trials, Javitt JC et al [19] , have

shown that the deduction and treatment of diabetic eye disease in both the US and Scandinavia is not only cost effective, but is actually cost saving. Potential savings in the USA exceed \$600 million annually, while in Sweden potential savings of SEK 36 million may be realized.

KB Johnsen [20] has shown that in type-1 diabetes early detection of nephropathy by screening for micro albuminuria and immediate resource to improved control with anti-hypertensive medication not only increases life expectancy significantly, but also at the same time reduces total health care costs.

In the Bangalore Urban Diabetes (BUD) Study [21], it was noted that with similar diabetes duration twice as many persons aware of diabetes and its consequences were free of complications as compared to those who were not aware.

From the data based on published results and use of computer modeling, Hermann and Eastmann [22] have shown that comprehensive care will bring about substantial reduction in complications as compared to standard care. These benefits accrue for eye disease, and stage renal disease and lower extremity amputations.

The absence of a proper infrastructure and protocol based care for diabetes may result in disastrous consequences.

## **BARRIERS TO GOOD DIABETES CARE**

### **Infrastructure and Socio-Economic :**

Being a chronic disease, diabetes requires support service infrastructure and team approach to care. Whereas, generally the level of clinical care in most big cities in India is good, lack of support system, non availability of trained paramedical personnel , no health care insurance for chronic disease such as diabetes, continue to be problematic. There are few diabetologists. Private practicing general practitioners and internists provide primary care even in urban areas. The quality of care varies considerably from place to place and practice to practice depending upon the physician's interest, expertise and available infrastructure. Given the massive load of acute illnesses such as infections, fever, infestations etc. private medical practitioners, tend to concentrate less on chronic disease like diabetes, which are unrewarding as the time, effort and commitment needed is far too much , both for

the provider and patient . There are practically no nurse educators, no podiatrists, and few dieticians, which means that the treating doctor takes the entire burden of responsibility of caring for these patients. The patient's inability/unwillingness to pay for these additional support services also hinders the development. Lack of medical reimbursement and poor state funding for health, is a barrier to quality care, because the patient is unable to afford certain tests or therapy.

**Table 2 :Lab Tests/Clinical Examination ever undertaken. (BUD Study)**

<b>Test</b>	<b>Percent</b>
Urine examination	98.7
Blood Sugar	
Fasting	96.4.
Post Prandial	94.9
Glucose tolerance	66.1
Blood Lipids	7.7
Kidney Function	13.1
Blood Pressure check	23.6
Eye exam	18.0
Check for circulation/ sensation in legs	11.9
X-ray exam	17.0
ECG	20.6
Others	3.9

### **Poor Monitoring:**

To prevent diabetes complications, it is crucial that proper monitoring be carried out, first to assess the response to treatment and secondly to detect any complications. In the given socio-economic situation in India, the lack of proper health care infrastructure and support for chronic illnesses; the rampant ignorance and absence of clear cut, even barely minimum, guidelines on protocols for care and monitoring at the primary level means that diabetes care at this level is poor and the approach to the illness is ad-hoc . when resources are scant, and the option is to choose between monitoring and treating, it is quite understandable that monitoring is neglected and does not receive the attention it deserves. Many times of-course, it is not merely an issue of resources but knowledge about its need which is the biggest problem.

**Table 3: Missing data (Diab care Asia Study)**

Unavailable data (>5%)	Percent
Blood Pressure	6%
Level of education	5%
Local HbA1c	92%
Serum triglyceride	46%
Serum cholesterol	36%
HDL cholesterol	58%
Serum creatinine	36%
Albuminuria	90%
Proteinuria	25%
Retinopathy	6%

This problem of monitoring is highlighted in the Bangalore Urban Diabetes Survey [21,23]. In this study only 7 respondents out of 611 (1.1%) undertook home monitoring of blood glucose. Table 2 provides the list and frequency of various lab and clinical tests that the respondents in this study indicated as having undergone. Lipid analysis, kidney function tests, x-ray, ECG etc. were either not done or carried out only in a few patients. Even simple clinical examination of the feet, measurement of blood pressure and examination of the eye was not done in over 80% of the cases. Similar findings were noted in other studies as well [24,25].

The results of Diab Care-Asia study [24] indicate that type 2 diabetes begins earlier amongst Indians. Despite claims to the contrary, obesity is an important association of diabetes in urban India (higher BMI in approximately 40% patients). Glycemic control is generally less than adequate and deteriorates with increasing duration of diabetes. Self-monitoring is poor even amongst patients attending tertiary care urban centers. Over 55% of patients manifest late diabetic complications at a mean duration of diabetes of 10 years. Table 3 shows the data missing from patients' case records even at the tertiary diabetes care centers. The rate and frequency of self or lab based blood glucose monitoring in India was one of the lowest amongst the countries participating in the Diab care Asia study and HbA1c was amongst the highest [26].

### **Physician Related issues :**

Most of the patients, (over 70%), initially visit a non-specialist for diagnosis. It is this segment of doctors who are the most important link in early diagnosis and guiding the patient properly, but are often ill-trained to handle diabetes related issues,

unaware of the latest trends, or unable to devote time to diabetes due to their busy practice.

An important but generally un-researched dimension is health care provider behavior. Physicians are trained to provide acute care, where effort and success is easily measurable and is linked to a sense of achievement and power. Need for patient involvement and participation in therapeutic decision making is limited.

In chronic diseases this "mind set" doesn't work. There are no heroic efforts, no dramatic results (no cure), moreover, the patient may be asymptomatic, unaware or unwilling to comprehend consequences of long term poorly managed disease. The physicians position of power and minimal need of patient involvement prevailing under acute conditions does not work and requires different physician behavior-that of a councilor, a friend or family elder. This role transition is difficult in the setting of overburdened services and limited time. In good faith, physicians make decisions for the patients. Many have misplaced concerns about their patients fear, apprehensions and capability for self-care. These impressions are coloured by the "acute care" mind set and physicians' own feelings and are at best subjective and empirical. The inability / unwillingness to discuss treatment options and the patients inability (due to inadequate information) to initiate such discussions deprives him/her the opportunity to actively participate in management.

Are the doctors' perceptions of patient worries in line with the worries and problems patients actually face? There appears to be a gap in perceptions in the actual problems and the worries that patients have and physicians' perception which makes one wonder –do physicians underestimate their patients' ability to learn and cope with insulin therapy when faced with it? Or is it that there are other barriers to effective and methodical approach to diabetes management?

In a still largely traditional society, the physician's attitudes do influence the patients and this is an important consideration. A recent study [16] mentions how clinical interactions between the doctor and patient can unwittingly create barriers to insulin. The authors of this study mention that patients often spoke of health care providers using insulin as a threat to promote behavioral changes, or as a punishment for failure to comply or as a bargaining tool in promising its withdrawal as a reward for behavioral change. While this works in

the short term, to get desired results, in the long run it creates the impression that insulin is something that must be avoided and thus only serves to increase reluctance and increase barriers to it. The health care providers ability to motivate a patient to change his/her attitude and behavior to an illness or accept a certain line of treatment can influence long-term prognosis [17].

The general lack of confidence on part of the treating physician as to how much self care person with diabetes can manage maybe because of – the paucity of facilities to train persons with diabetes in self care techniques, or due to economic consideration and an over-reliance on hospital setting [15].

The other possible barriers as revealed from a previous study [15] are

Improper understanding of the relevance of monitoring and its implication in treatment decision-making or treatment modification. This is clear from the low frequency, mode and site of checking, and application of results to modify treatment and understand the need for further intervention in case of a co-morbid complication. Absence/lack of familiarity to widely acceptable simple protocols to guide the health care provider as to when to employ specific modes of therapy; as brought out by no uniform glucose level to institute insulin therapy for persons with type 2 diabetes.

Misapprehensions fear and worry about potential side effects in general and hypoglycaemia in particular.

Comprehension of detailed information relating to insulin seems to be lacking.

Inadequate training and occasional contact with diabetic patients amongst the non-specialist doctors maybe another important barrier. As noted earlier, providing diabetes care requires a different approach and mind set.

The complexity of treatment and the very many options available, make physicians reluctant to attempt something different from what was initiated earlier, despite the progressive nature of the illness.

### **NEED FOR BASIC MINIMUM PROTOCOLS OF CARE**

More non-specialists are seeing increasingly more diabetics and ascribe this to its increasing prevalence. They now use insulin to treat type 2 diabetics more often than about five years ago, as they have become aware of the long-term complications and the importance of metabolic control in its prevention, as well as the limitations of oral drugs. There is an increasing trend to use insulin for short periods during an emergency. Like patients, even non-specialist doctors feel an overwhelming need and willingness to participate in education programmes on diabetes. Some of them express the need for programmes to help them understand patient needs and techniques for counseling. This points to guidelines on diabetes care, which must then be uniformly followed. Thus it appears that there is a growing awareness amongst health care providers about the lacunae in diabetes health care delivery in India.

Proper control can prevent, retard or arrest development of complications both in type 1 and type 2 diabetes as shown by the DCCT, UKPDS Kumamoto, and numerous other studies. Without effective intervention, the diabetes epidemic will continue to grow. Effective intervention means prevention and prevention means primary prevention –life style changes, and secondary prevention –reducing the burden of complications, by early diagnosis and proper care.

There is an urgent need to develop simple cost effective protocol for care, which cover "Basic Minimum Standards". Such protocol must become part of basic medical education. Efforts must be directed to empower, encourage and educate primary care physicians to use these basic standards.

There is a need to improve case record maintenance, develop registries and carry out comes research to refine standards and identify "at risk" patients. Large-scale efforts to improve awareness and knowledge amongst those affected and their families as well as population at large are needed.

Action taken early in the course of diabetes is more beneficial in terms of quality of life and is more cost effective, especially if it can prevent hospitalization. Proper management requires investment in awareness, education and better care.

Providing health care to prevent and treat diabetic complications requires resources. The cost of not doing so will be phenomenal.

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